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<p>The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of two common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implants and transverse rectus abdominis musculocutaneous (TRAM) flaps. A four year prospective study, the project seeks to adapt existing instruments and formulate new methodologies to assess outcomes in five categories; complication rates, aesthetic results, functional results, psychosocial status and costs. Measurements of outcome variables are obtained prior to reconstruction and at annual intervals starting one year after the procedure. Instruments used include questionnaires, physical testing, evaluation of digitized photographs and analysis of billing and hospital record data. Since the project was initiated in September, 1994, 100 patients have been recruited in collaboration with 12 plastic surgeons and 8 medical centers across southern Michigan. Although only preoperative testing has been conducted thus far, study participants have included women undergoing expander/implant (31%) and TRAM procedures (69%). Ultimately, a total of 450 patients will be enrolled in the project. These women will be followed for two years from the time of reconstruction. During the past year, additional work has been conducted to <u>develop and test instruments for outcomes assessment in breast reconstruction</u>.</p>		
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Edwin G. Wilkins 7/17/95

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ABSTRACT

The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of two common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implants and transverse rectus abdominis musculocutaneous (TRAM) flaps. A four year prospective study, the project seeks to adapt existing instruments and formulate new methodologies to assess outcomes in five categories: complication rates, aesthetic results, functional results, psychosocial status and costs. Measurements of outcome variables are obtained prior to reconstruction and at annual intervals starting one year after the procedure. Instruments used include questionnaires, physical testing, evaluation of digitized photographs, and analysis of billing and hospital record data.

Since the project was initiated in September, 1994, 100 patients have been recruited in collaboration with 12 plastic surgeons and 8 medical centers across southern Michigan. Although only preoperative testing has been conducted thus far, study participants have included women undergoing expander/implant (31%) and TRAM procedures (69%). Ultimately, a total of 450 patients will be enrolled in the project. These women will be followed for two years from the time of reconstruction. During the past year, additional work has been conducted to develop and test instruments for outcomes assessment in breast reconstruction.

INTRODUCTION

Background and Relevance

Each year in the United States, breast cancer strikes over 180,000 women. Although most of these patients are candidates for breast-conserving therapy (usually in the form of lumpectomy and postoperative radiation), many still undergo mastectomy. Loss of one or both breasts constitutes a major psychosocial stress for women already struggling to cope with a life-threatening illness. The disruptions in body image, interpersonal relationships, and other aspects of psychosocial functioning which result from mastectomy often have a significant negative effect on the recovering cancer patient's quality of life.

Previous research has clearly demonstrated the benefits of breast reconstruction for women undergoing mastectomy. Whether performed at the time of mastectomy or as a later secondary procedure, breast reconstruction may prevent or reverse many of the emotional and psychological disturbances seen in women undergoing mastectomy. Common sequellae such as impaired sense of well-being, compromised femininity, decreased feelings of sexual desirability can be reversed by the restoration of form and function.

Based on recent figures, there is a growing public acceptance of and demand for breast reconstruction. The American Society for Plastic and Reconstructive Surgeons estimates that 43,000 of these procedures were performed by its members during 1990. In 1990 (the most recent year for which data is available), expander-implant techniques constituted the majority of procedures for breast reconstruction. However, with the recent controversy over the safety and effectiveness of silicone gel breast implants, natural (autogenous) tissue techniques, most notably the transverse rectus abdominis musculocutaneous (TRAM) flap, have become increasingly common. Although they avoid the potential complications of prosthetic implants, TRAM flaps are more complex and expensive procedures. Given the growing prevalence of breast reconstruction in the United States, expander-implant and TRAM procedures are responsible for an annual outlay of health care dollars in the hundreds of millions.

Although considerable resources are currently being spent on breast reconstruction, relatively little information is available on comprehensive long-term outcomes of this treatment modality. There is a critical need for statistically credible research which reflects not just the technical feasibility and aesthetics of breast reconstruction, but which also shows the functional, psychological, and social benefits of such procedures. Finally, these demonstrated benefits of reconstruction must be assessed in relation to the costs of such operations. In essence, we must demonstrate the *value* of breast reconstruction.

Objectives

The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of the two most common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implants and transverse rectus abdominis musculocutaneous (TRAM) flaps. A four year prospective study, the project is adapting existing instruments and formulating new methodologies to assess outcomes in five categories: complication rates, aesthetic results, functional results, psychosocial status and costs. Study results will provide much needed information to patients, providers, and payers for determining the procedure of choice. In addition, the research will establish standardized methods for evaluation of breast reconstruction results in future studies. Finally, initial data assembled by this research can also be used for long-term analysis of breast reconstruction outcomes.

Purpose/ Hypotheses

The purpose of the proposed research is two-fold: (I.) to develop a standard set of instruments for the evaluation of outcomes from breast reconstruction; and (II.) to use these instruments to compare outcomes for patients undergoing expander/implant reconstruction and those receiving TRAM reconstruction.

I. To achieve the first objective, multiple hypotheses will be tested:

- (1) Less costly clinical evaluations of functional outcomes have predictive validity (i.e., correlate highly with measures obtained from more costly isokinetic muscle testing).
- (2) Clinical evaluations of functional outcomes are reliable.
- (3) Less costly subjective assessments of both aesthetic and functional outcomes have predictive validity (i.e., correlate highly with more costly, objective measures).
- (4) Condition-specific, subjective assessments of functional and psychosocial outcomes have greater predictive validity than generic, subjective assessments.
- (5) Subjective assessments of aesthetic, functional, and psychosocial outcomes are reliable.

The results from testing the above hypotheses should identify the set of instruments which provide the most valid and reliable data at the lowest possible cost.

II. To achieve the second objective, multiple outcome measures of expander/implant and TRAM reconstructions will be assessed. The following null hypothesis will be tested for comparing outcomes from the two reconstruction procedures:

- (6) For expander/implant and TRAM procedures, there will be no differences in the five measured outcomes: (a) complication rates; (b) aesthetic results; (c) functional results; (d) psychosocial status; and (e) overall costs

Summary of Methods

Using patients recruited from the practices of 22 plastic surgeons and 10 medical centers across southern Michigan, the Michigan Breast Reconstruction Outcome Study (MBROS) is a prospective study comparing the outcomes of expander/implant and TRAM reconstructions. As noted above, outcomes measured include complications, aesthetic results, functional results, psychosocial status, and costs. Patients are followed for two years: function and psychosocial status are assessed preoperatively, while all five outcome parameters are measured postoperatively at one year intervals.

The proposed research is a non-equivalent treatment group, multi-factor, full factorial design, with pre-test and post-test data collected prospectively. The two treatment groups are (1) patients undergoing breast reconstruction using tissue expansion/implants, and (2) patients undergoing reconstruction using TRAM flaps.

The multi-factor aspect of the proposed research design, as well as the use of pre-test and post-test measures for several of the outcomes of interest, are intended to control for the differences in the patient populations between the two procedure

groups. The factors to be included in the design, plus the number of levels of each, are described below:

- (1) Procedure type; two levels: (a) tissue expanders/implants and (b) TRAM flaps
- (2) Timing of procedure; two levels: (a) *immediate* (reconstruction at the time of mastectomy) and (b) *delayed* (reconstruction months or years following mastectomy)
- (3) Scope of procedure; two levels: (a) unilateral and (b) bilateral.
- (4) Surgeon; 17 levels (one for each surgeon who has agreed to participate).

The pre-treatment measurements of outcome variables are obtained prior to surgery. Post-treatment measurements will be collected at a minimum of two different time points after surgery. This approach will identify the cumulative effect of some measures (e.g., complications and costs) and will help determine the earliest time point at which the other outcomes stabilize (e.g., functional and psychosocial status). The post-treatment data collection periods will be at one year following surgery and at annual intervals thereafter. Two of the outcome measures, complication rates and costs, will be measured post-treatment only, as they are characteristics of the treatment itself, and therefore, have no pre-treatment measures.

As noted above, MBROS will study five outcomes of breast reconstruction: complications, aesthetic results, functional results, psychosocial status, and costs. A variety of methods are being used to measure these parameters: in some cases, existing instruments are being employed in their original form, while in other instances, existing methodology is being modified to better assess the outcomes of interest. New techniques are also being tested for several of the five outcome parameters.

Postoperative complications will be assessed with hospital chart and office record reviews at the conclusion of each patient's two year study participation. *Aesthetic results* will also be evaluated on the second anniversary following reconstruction using three different approaches: (1)computer analysis of digitized postoperative photographs; (2)physician ratings of post-operative photographs; and (3)patients' assessments of their own aesthetic results. Back, abdominal wall, and shoulder *function* is being examined preoperatively and at one and two year intervals after surgery with objective assessments (Cybex isokinetic testing). The effects of reconstruction on physical functioning are also being studied with activities of daily living (ADL) items on the study questionnaire administered at the same time intervals. To examine *psychosocial outcomes*, the preoperative and postoperative study questionnaires contain condition-specific questions as well as a battery of existing instruments including the SF-36, Basic Symptom Inventory (BSI), Modified Somatic Perception Questionnaire (MSPQ), and the Functional Assessment of Cancer Therapy (FACT). Finally, *costs of reconstruction* will be assessed at the conclusion of each patient's two year participation using hospital billing data in Relative Value Units (RVUs).

BODY

Project Status

MBROS was funded by the U.S. Army in July of 1994 for a four year period. After the hiring and training of project personnel, the study was initiated in late September, 1994. As described in the Statement of Work (SOW) included in the proposal, the goals for the first year of the project are listed below. Progress made during the past year towards completion of each milestone is also detailed.

MBROS Statement of Work (Months 1-12)

A. Set up database in UM Cancer Center.

Utilizing FoxPro software on a Power Macintosh system, a linked database was developed in the UM Outcomes Research Office which can accommodate the results of participants tested. Each individual study patient generates 1,120 unique fields of data which are maintained both on the computer system and on locked hard copy files. Patients are assigned unique identification codes which are used throughout all data input and reporting to protect the identities of individuals.

FoxPro is one of the fastest and most flexible relational database management systems available for the Macintosh. Analysis of the collected data can be accomplished quickly and efficiently utilizing its statistical programs, and cross-platform functionality. Attached to this report are hard copies of the data input screens developed and utilized by MBROS personnel to protect the actual databases from possible entry error or destruction.(See Appendix B) Additionally, monthly studies are conducted by randomly selecting hard-copy patient records and verifying the integrity of the data input, with a resulting 99.2% accuracy rate.

B. Refine aesthetic rating scale to be used by surgeon-evaluators.
Test interrater and intrarater reliability.
(Modification of Garbay Scale Criteria:)

One of the objectives for the first year of the study was to modify the criteria of a commonly used ordinal scale for rating the aesthetic results of breast reconstruction. As reported in the original proposal, a study of the reliability of three commonly used scales showed poor reliability on two scales, with fair reliability on a third. Our objective was to make the criteria of the third more explicit, to improve its reliability further. Below are the original criteria and the revised criteria of the scale.

Two of the three raters (plastic surgeons) who participated in the original reliability study used the modified criteria to rank 47 of the original 50 photographs, plus four new photos. Interrater reliability between the two raters using the original criteria and the modified criteria was calculated using a pair-wise kappa statistic. The results show a significant improvement in reliability for the volume scale, but a decrease in reliability for the placement, infra mammary fold, and scar scales.

Table A:
Inter-Rater Reliability (Pair-Wise Kappa),
Original vs. Modified Criteria for Aesthetic Ratings

	Original Criteria	Modified Criteria
Volume	.26	.38
Contour(shape)	.35	.38
Placement	.54	.36
Infra mammary fold	.30	.23
Scars	.30	.10

After the two raters completed their ratings, their responses were reviewed with them, and those cases on which they disagreed were discussed. As a result of that discussion, the following improvements are going to be made to make the scale criteria even more explicit:

(1) A fourth category will be added to each subscale to reflect a result that is less than perfect but better than "marked" or "noticeable" differences - to reflect differences that are noticeable to the naked eye but that are minor in terms of the range of "normal" (unreconstructed) breasts and of feasible outcomes.

(2) All criteria will be specified relative to something-either "perfect" breasts, "normal" breasts, or the best possible outcomes given surgeons' skills and available technology. The selected standard for comparison will be explicitly defined.

(3) The criteria will emphasize that each subscale should be rated independently of the others, i.e., if the overall result is good, but the result in one subscale is not so good, the rating of that subscale should not be elevated to reflect the overall result.

(4) Sample photos will be provided for each category of each subscale. even though it will not be possible to provide photos covering all possible defects, they can provide a reference point, which is needed. Otherwise, raters tend to base their responses relative to the cases they have reviewed prior to this, which is not desirable.

New criteria which incorporate the above recommendations will be devised and tested within the next six months.

	Original Criteria*	Modified Criteria*
Volume		
0	Marked Discrepancy	Asymmetry of at least 1 cup size
1	Mild discrepancy	Noticeable asymmetry, but < 1 cup size
2	Symmetrical	No significant visible asymmetry
Contour(shape)		
0	Marked deformity/ asymmetry	Marked deformity or asymmetry: -obvious difference in degree of ptosis(mild vs. moderate, moderate vs. severe, etc.) -excessive superior bulk in reconstructed breast likely to be visible in bra and clothing - noticeable contour defects including severe wrinkling, skin retraction, etc.
1	Mild deformity or asymmetry	Mild deformity or asymmetry -differences in ptosis less than a full degree or level(i.e., mild, moderate, severe) -excess superior bulk but not to extent likely to be visible in bra or clothing -visible but relatively minor contour defects such as subtle wrinkling, small areas of retraction
2	Natural and symmetrical	Natural appearing and symmetrical
Placement relative to midline/anterior		axillary line
0	Marked displacement	Marked medial or lateral displacement
1	Mild displacement	Minor medial or lateral displacement
2	Symmetrical and aesthetic placement	Aesthetic and symmetrical medial placement
Inframmary Fold		
0	Poorly defined/not identified	Poorly defined or not defined on reconstructed breast; fold defined on reconstructed breast but with superior or inferior displacement > 2 cm
1	Defined but with asymmetry or lack of medial definition	Defined on reconstructed breast but with superior/inferior displacement up to 2 cm and/or lack of medial definition
2	Defined and symmetrical	Well-defined and symmetrical
Scars		
0	Hypertrophy, contracture	Hypertrophic and/or contracted
1	Wide scars, poor color match but with hypertrophy or contracture	At least 5 mm in width with or without poor color match, no hypertrophy or contracture
2	Thin scars, good color match	Scars < 5 mm in width, good color match

*all criteria refer to a comparison of the treated breast with the untreated breast

C. Test interrater and intrarater reliability of Cybex functional testing.

The functional assessment of the reconstructed patient is an important outcomes measurement, particularly with the use of one or both rectus abdominis muscles for reconstruction as is done with the TRAM technique. Isokinetic testing was selected for this study to provide a more objective, quantitative, and reliable measure of abdominal muscle strength.

Since patients will be tested multiple times during the project in order to evaluate the functional effects of surgery over time, it is important that the intra-rater reliability of these measurements over time be established. Any differences observed in patients' strength over time should *not* be due to differences in measurement methods.

A consultant with expertise in physical therapy and research experience in a variety of isokinetic measurements was selected to in-service the physical therapy staff at each of the functional assessment sites during the month of August, 1995. Each in-service included a review of the study protocol, as well as a hands-on demonstration of protocol administration utilizing a staff member as the subject.

Following the completion of training, intra-rater reliability at one of the sites (Saline Physical Therapy) was evaluated. Ten women volunteers were tested and retested at the same site by the same physical therapist two weeks later. For each of the measurements of interest, a paired *t* test comparing the measures at the two different time periods on each subject was performed. The *P* -values are presented below.

<u>Variable tested</u>	<u>Prob > T </u>
5. shoulder flexion	0.1679
6. shoulder abduction	0.2781
7. shoulder external rotation	
8. shoulder internal rotation	
9. trunk flexion	0.2781
10. trunk extension	0.3571

KNEE EXTENSION/FLEXION: CONCENTRIC FLEXORS

11. peak torque @ 90	0.4061
12. peak torque @ 180	0.0428****
13. total work @ 90	0.7381
14. total work @ 180	0.1915
15. avg power @ 90	0.4164
16. avg power @ 180	0.0563

KNEE EXTENSION/FLEXION: CONCENTRIC EXTENSORS

17. peak torque @ 90	0.4886
18. peak torque @ 180	0.0284****
19. total work @ 90	0.4457
20. total work @ 180	0.8974
21. avg power @ 90	0.5266
22. avg power @ 180	0.1424

SHOULDER ROTATION: CONCENTRIC EXTERNAL ROTATORS

23.	peak torque @ 90	0.7052
24.	peak torque @ 180	1.0000
25.	total work @ 90	0.1578
26.	total work @ 180	1.0000
27.	avg power @ 90	0.1520
28.	avg power @ 180	0.6483

SHOULDER ROTATION: CONCENTRIC INTERNAL ROTATORS

29.	peak torque @ 90	0.8082
30.	peak torque @ 180	0.1582
31.	total work @ 90	0.9561
32.	total work @ 180	0.0188*****
33.	avg power @ 90	0.6662
34.	avg power @ 180	0.0005*****

TRUNK EXTENSION/FLEXION:CONCENTRIC FLEXORS

35.	peak torque @ 90	0.7062
36.	peak torque @ 180	0.7400
37.	total work @ 90	0.0781
38.	total work @ 180	0.2553
39.	avg power @ 90	0.4383
40.	avg power @ 180	0.5757

TRUNK EXTENSION/FLEXION:CONCENTRIC EXTENSORS

41.	peak torque @ 90	0.7898
42.	peak torque @ 180	0.2199
43.	total work @ 90	0.4940
44.	total work @ 180	0.7794
45.	avg power @ 90	0.6637
46.	avg power @ 180	0.3633

SHOULDER EXTENSION/FLEXION:CONCENTRIC FLEXORS

47.	peak torque @ 90	0.1654
48.	peak torque @ 180	0.3523
49.	total work @ 90	0.2897
50.	total work @ 180	0.4495
51.	avg power @ 90	0.3452
52.	avg power @ 180	0.5919

SHOULDER EXTENSION/FLEXION:CONCENTRIC EXTENSORS

53.	peak torque @ 90	0.8825
54.	peak torque @ 180	0.7730
55.	total work @ 90	0.1727
56.	total work @ 180	0.5718
57.	avg power @ 90	0.4280
58.	avg power @ 180	0.3794

Values with ***** indicate a significant difference between the two time periods at the $\alpha = .05$ level. The four measures that differed significantly were:

- 1.knee extension/flexion: concentric flexors with peak torque @ 180;
- 2.knee extension/flexion:concentric extensors with peak torque @ 180;
- 3.shoulder rotation:concentric internal rotators with total work@ 180; and
- 4.shoulder rotation:concentric internal rotators with avg power @ 180

Peak torque, the primary functional outcome indicator of interest, demonstrated good intra-rater reliability for all variables except knee extension/flexion. The latter functional parameter was initially included in the isokinetic testing protocol as an additional control. Although work continues to improve the intrarater reliability for all aspects of these assessments, evaluation of knee function is not considered a vital component of isokinetic testing in breast reconstruction patients.

While the results obtained from this one site demonstrated good reliability and indicated the effectiveness of the training program, we intend to evaluate intra-rater reliability on an ongoing basis at all of the sites, beginning in August 1995, as part of an effort to ensure the quality of the functional assessments. These evaluations will be repeated again in years 1996 and 1997, to determine if training needs to be repeated.

Inter-rater reliability among the physical therapy sites was not tested because preoperative and postoperative assessments will be carried out at a single site for each patient. Study participants will not be allowed to change physical therapy sites from one evaluation to the next. The analysis of functional outcomes in this study will be based only on gain scores--i.e., the difference in scores for a given patient on the same Cybex machine across time. Therefore, if the equipment at the various sites is calibrated differently such that the values of the measurements are not necessarily equivalent across sites under the same circumstances, it is neither necessary nor appropriate to compare these values across sites. Use of gain scores obtained across time on the same device will eliminate any differences due to calibration or technique across sites.

D.Proceed with patient recruitment (225 patients in first year).

In this study, the principal investigator must rely on the cooperation of other participating physicians to recruit patients to the project. Initially, the participating physicians contributed less study patients than had originally been projected.. However, following additional educational meetings by the principal investigator and research study coordinator with physicians and their office staffs as to enrollment procedures, participation climbed sharply to its current level of approximately 4 to 5 new patient enrollees each week.

PATIENT ENROLLMENT BY MONTH: YEAR# 1 MBROS

SEPTEMBER,1994	5
OCTOBER,1994	7
NOVEMBER,1994	5
DECEMBER,1994	0
JANUARY,1995	8
FEBRUARY,1995	15
MARCH,1995	9
APRIL,1995	15
MAY,1995	21
JUNE,1995	5
JULY (first 2 weeks)	<u>10</u>
TOTAL	100

Patient enrollment by physician for the time period September 1,1994 to July 14, 1995 is shown below: MICHIGAN BREAST RECONSTRUCTION OUTCOME STUDY, YEAR I

PHYSICIAN	# OF PATIENTS	# OF TRAMS	# OF IMPLANTS	# OF IMMEDIATE	# OF DELAYED	HOSPITAL
Wilkins, Edwin	22	15	7	16	6	Univ of MICH
Shaheen, Ken	19	9	10	3	16	Beaumont
Izenberg, Paul	17	13	4	14	3	St. Josephs
Houin, Herman	11	10	1	4	7	Henry Ford
Beil, Richard	6	6	0	6	0	St. Josephs
Hammond, Dennis	6	4	2	5	1	St. Mary's
Schenden, Michael	4	1	3	1	3	Beaumont
Bengston, Bradley	3	1	2	3	0	Holland Comm
Drever, Michael	6	6	0	0	6	Tor General
Darian, Vegan	4	3	1	2	2	Henry Ford
Nelligan, Peter	1	1	0	0	1	Women's Coll
Smith, David	1	0	1	1	0	Univ of MICH
TOTAL	100	69	31	55	45	

In order to further encourage patient enrollment, a decision was made to offer a per study enrollee reimbursement of \$30.00 to referring physicians in order to offset the cost of personnel time needed to enroll and maintain patients in the study. This reimbursement will go into effect in August, 1995.

Of the 100 patients enrolled, 15 have been withdrawn from the study due to :

- (1) not completing either the pre-operative questionnaire or functional assessment prior to surgery (8 patients or 53.3%);
- (2) inability to physically complete the functional assessment because of other health problems (2 patients or 13.3%);
- (3) patient changed her mind about wanting to participate (2 patients or 13.3%);
- (4) patient canceled her surgery(2 patients or 13.3%)
- (5) patient should not have been enrolled in study because she was a revision and not an initial reconstruction (1 patient or 6.7%).

Over half of the withdrawn patients can be attributed to the inexperience of the participating physician's office staff in enrolling patients in the study, and the need to have the patient complete all pre-operative requirements in a timely fashion. Errors of this type are no longer as significant a problem as the involved personnel move up the learning curve of enrollment procedures.

E. Administer preoperative functional tests and questionnaires to patients enrolled in study. Give patients instructions for maintaining log of outpatient visits and services received. Perform monthly follow-up of log data.

In order to assure the accurate and timely collection of patient data, procedures for patient enrollment and data maintenance were developed. Each participating physician was provided with several patient packets which include the following literature: (See Appendix A)

- marketing/invitational brochure
- general information sheet
- two informed consent forms
- pre-surgical questionnaire
- directions to appropriate physical therapy facility
- physicians post-surgical outpatient log
- postage paid return envelope for questionnaire

Physicians were instructed to discuss the MBROS with all patients who met the clinical guidelines for the study, and offer the opportunity to each of these women to participate.

Once the patient makes the decision to enroll, the physician/office staff obtain the appropriate initials and signatures on the informed consent. The office staff then notifies the office of the study coordinator to provide the patient's name, date and type of surgery, and telephone.

Each study patient is assigned a unique identification number which is used in all data compilation. The patient is contacted directly by the study coordinator to:

- (1) arrange a mutually agreeable time for the functional assessment with the patient and with the physical therapy personnel. Results of the test are later mailed directly to the MBROS office for data input and analysis.
- (2) briefly review the pre-surgery questionnaire, stressing the importance of pre-operatively completing the document, which is then mailed directly to the MBROS office in a provided stamped, addressed envelope. (Copies of the pre-operative and post-operative questionnaires are attached).
- (3) discuss the post-operative patient log maintenance requirements. The log is collected every 3 months by the MBROS personnel. Study participants who fail to return their logs in a timely fashion are contacted by telephone to encourage their compliance.

F. Review data from pre-operative tests and questionnaires to verify surgeon, physical therapist, and patient compliance with study protocol. Resolve any problems using telephone follow-up or site visits.

Data from the various sources is reviewed on an on-going basis to verify completion of all survey instruments, and for the purposes of follow-up reporting and billing. In the event of incomplete data, the missing instruments are identified, and appropriate actions taken to obtain the data pieces. In some cases, patients have had to be withdrawn from the study, primarily because they have either not completed their functional assessment or their pre-operative questionnaire in a timely fashion (i.e., prior to their surgery). In such cases, the patient and their physician are notified that the patient is no longer eligible for participation.

G. Obtain preliminary cost data from participating hospitals and surgeons on patients enrolled during first six months of study, to establish cost data base and to identify any potential problems in obtaining the data and linking records. Merge inpatient cost data with outpatient data obtained from patient logs.

The comparison of costs between the TRAM and implant methods of reconstruction is one of the five categories in which patient outcomes will be studied. The total cost of treatment for each study patient will consist of all professional and hospital costs associated with the patient's hospitalization for the reconstruction, plus the costs of any subsequent care received (inpatient or outpatient) that is related to the reconstruction. For those patients undergoing delayed reconstruction, the professional and hospitalization costs associated with the original mastectomy will also be included, to ensure comparability of costs with those of immediate reconstruction patients.

Because of the lack of standardization across hospitals in the relationship of costs to charges, the measurement of costs for this research is carried out using Relative Value Units (RVUs). RVUs have been determined for each of the University of Michigan Hospital's fee codes by multiplying the ratio of an individual fee codes charge to a department's total charges by the department's total direct costs: (indirect costs are excluded from the calculations).

Hospital charge/billing information is typically incomplete for a period of three to six months following the rendering of patient services. Analysis of patient costs data has begun for UM patients utilizing the RVU system previously discussed. Components of total financial costs are:

- **Category A:** hospital costs, i.e., operating room, associated costs, and room costs
- **Category B:** professional fees, I.E., reconstructive surgeon and anesthesiology costs
- **Category C:** previous anesthesiology and hospital costs for delayed mastectomy
- **Category D:** facility and anesthesiology costs for explantation of tissue expander
- **Category E:** complication from reconstruction costs

Costs from other institutions will be collected starting in September, 1995, and mapped to the UM RVU system in order to assure accurate comparison.

CONCLUSIONS

In the next twelve months, work within MBROS will concentrate on several areas:

- (1) Continue to refine and test instruments to assess breast reconstruction outcomes. Methodology for evaluating aesthetic and functional results will undergo further reliability testing.
- (2) Sustain an adequate rate of new study participant recruitment through persistent physician and patient education.
- (3) Initiate postoperative outcome assessments for women enrolled during the first year of the project. Evaluation of complications, function, and psychosocial status following reconstruction will begin. Aesthetic and cost analyses of these early patients will be carried out two years post-reconstruction.

As noted earlier, the objectives of MBROS are two-fold: (I.) to develop a standard set of instruments for the evaluation of outcomes from breast reconstruction; and (II.) to use these instruments to compare outcomes for patients undergoing expander/implant reconstruction and those receiving TRAM reconstruction. Significant progress towards achieving the project goals has been accomplished during the first year. Recruiting patients into the study and maintaining adequate follow-up present the greatest challenges for the coming twelve months. However, with enrollment rates growing and participant attrition declining, the study patient population should prove more than adequate to meet the demands of the project design.

By accomplishing its objectives, MBROS will yield several important benefits. Instruments developed, refined and tested during the project can be used by other investigators for the ongoing monitoring of the quality of breast reconstruction. MBROS will yield information for use by patients and health care providers in selecting breast reconstruction procedures. Finally, completion of the project will produce a multicenter database for ongoing studies on the long-term outcomes of breast reconstruction.

PRESENTATIONS

Wilkins EG, Lowery JC and Kuzon WM: "Evaluation of Aesthetic Results in Breast Reconstruction" American Society of Plastic and Reconstructive Surgeons, September, 1994, San Diego, California

Wilkins EG, Lowery JC and Kuzon WM: "Evaluation of Aesthetic Results in Breast Surgery" : Breast Surgery in the Nineties. Symposium sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia

Wilkins EG, "Outcomes Research in Breast Surgery": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia

APPENDIX A
PATIENT MATERIALS



*We believe you can
improve the lives
of thousands
of other women.*

Will you help?

Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor



We'd like you to participate in a research study that will try to compare the benefits of the two most popular types of breast reconstruction for breast cancer patients: (1) the expander-implant technique and the (2) TRAM flap. You will decide, along with your physician, which is the most appropriate treatment for you — that doesn't change because of the study. We simply want to ask you questions about yourself and to complete a physical therapy assessment of you. Your answers, and those of the other participants, will be used to help set new standards for breast reconstruction surgery and determine future health care policy.

There are only a few requirements for you, but your involvement in the study will benefit the more than 180,000 women diagnosed with breast cancer each year. If you decide to participate . . .

You will be required to:

- Answer a patient questionnaire before your surgery and then again one and two years after your surgery. The survey will ask about your feelings, concerns and other issues related to your reconstruction choice. The survey will take about one hour to complete.
- Allow a physical therapist to evaluate you before your surgery and then again one and two years after your surgery. The assessments will each take about one hour to complete. There is no additional cost to you or your insurance company for these evaluations.

You will **NOT** be required to:

- Pay any additional costs.
- Undergo any new tests, bloodwork or invasive procedures.

Please remember that you do not have to participate in this study. We will provide you with the same expert care regardless of your choice. We only ask that you strongly consider participating, as the results will benefit all women with breast cancer.



Information Sheet

Michigan Breast Reconstruction Outcome Study University of Michigan

Thank you for agreeing to participate in the Michigan Breast Reconstruction Outcome Study. By doing so, you are helping to shape future health care policies following mastectomy. We appreciate your taking valuable time to provide us with information regarding your own experience.

Below is a description of the process we will use to obtain your input to this study. If at any time you have any questions about the project, you may contact the project coordinator at (313) 936-7321 at the University of Michigan. (Please see the attached business card.)

1. While at your plastic surgeon's office, you were asked to sign a patient consent form to participate in this study. The signed form should remain with your surgeon and a copy of the consent is included in this patient packet for you. Any questions about the consent form should be addressed to the project coordinator.

2. Included in your patient packet is a tan patient questionnaire that you should complete as soon as possible. The questionnaire asks you to respond to a wide variety of questions which may sometimes seem repetitive; however, it is **very important** that you answer every question on the list so that we may include your responses in our study. The questionnaire should take less than an hour to complete. It may be helpful if you select a quiet time and place to work on it so that you are not interrupted.

3. Within the next few days, you will receive a telephone call from a representative within the project coordinator's office. He or she will answer any questions you may have, and will help you to schedule an appointment with a physical therapist at a location convenient to you so that we may conduct your pre-surgery evaluation. It is extremely important that this evaluation be done **before** your surgery so that we can compare it with your results after your surgery. There is no cost to you or to your insurance company for this evaluation, and like the questionnaire, it should take no more than one hour to complete. The machine that will be used is called a Cybex 6000, which measures muscle strength within your tolerance. Measurements will be taken of your stomach, arm and back strength and then compared against measurements one and two years after you have your surgery.

4. You should use the outpatient visit log to keep a record of any outpatient visit to **any** physician after your reconstructive surgery. Once every four months, we will ask you to mail in your log, and a new one will be sent to you. By keeping track of your outpatient physician visits, we will be better able to learn about the follow-up services that reconstruction may require. Remember, any physician visit, not just your plastic surgeon visits, should be recorded in the patient log.

Please return your questionnaire as soon as you have completed it. You may send it in the prepaid envelope provided to you. You should keep for yourself:

- this information sheet
- your copy of the consent form
- directions to the physical therapy office closest to you
- the project coordinator's business card
- the outpatient visit log

Again, we thank you for participating in this important and timely study. Through your efforts, we can make a difference in reconstruction policies following breast cancer.

2130 Taubman Center
1500 E. Medical Center Drive
Ann Arbor, MI 48109-0340

Off: (313) 936-7321

Post-Surgery Evaluation

Michigan Breast Reconstruction Outcome Study

University of Michigan, Ann Arbor

(For office use only)
REGISTRATION #

I. Personal Information

Today's Date: _____

Your Name: _____

Date of Birth: _____ SS#: _____

Address: _____

City, State, Zip: _____

Telephone: (home) _____ - _____ - _____ (work) _____ - _____ - _____

Contact person or relative who does not live with you:

Name _____

Telephone: (home) _____ - _____ - _____

Satisfaction with Surgery

We are interested in how satisfied you have been since your breast reconstruction. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. Knowing what I know today, I would definitely choose to have breast reconstruction.	1	2	3	4	5
2. The size and shape of my breasts are the same.	1	2	3	4	5
3. My reconstructed breast(s) feel soft to the touch.	1	2	3	4	5
4. Overall, I am satisfied with my reconstruction.	1	2	3	4	5
5. I would recommend the type of reconstructive procedure that I had to a friend.	1	2	3	4	5

General Health Survey

1. In general, would you say your health is: (Circle One Number)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

(Circle One Number)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

In one year from now, how do you think your health will be?

(Circle One Number)

Much better than today	1
Somewhat better than today	2
About the same as today	3
Somewhat worse than today	4
Much worse than today	5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on Each Line)	Yes Limited a Lot	Yes Limited a Little	Not Limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than one mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3
13. Bending over to brush your teeth	1	2	3
14. Sitting up in bed when you awake in the morning	1	2	3
15. Doing the dishes	1	2	3
16. Arising from a chair	1	2	3
17. Grasping for something, like reaching for a glass from the cupboard	1	2	3

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

(Circle One Number on Each Line)	Yes	No
18. Cut down the amount of time you spent on work or other activities	1	2
19. Accomplished less than you would like	1	2
20. Were limited in the kind of work or other activities	1	2
21. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
22. Cut down the amount of time you spent on work or other activities	1	2
23. Accomplished less than you would like	1	2
24. Didn't do work or other activities as carefully as usual	1	2
25. During the past four weeks , to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?		

(Circle One Number)

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

26. How much **bodily** pain have you had during the **past four weeks**?

(Circle One Number)

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

27. During the **past four weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework?)

(Circle One Number)

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

For each of the following statements, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
28. My breasts are without pain.	1	2	3	4	5
29. My abdomen is sore and painful.	1	2	3	4	5
30. I am frequently troubled by headaches.	1	2	3	4	5
31. My abdomen feels tight.	1	2	3	4	5
32. I have back pain.	1	2	3	4	5

These questions are about how you feel and how things have been with you **during the past four weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past four weeks** . . .

(Circle One Number on Each Line)	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
33. Did you feel full of pep?	1	2	3	4	5	6
34. Have you been a very nervous person?	1	2	3	4	5	6
35. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Did you have a lot of energy?	1	2	3	4	5	6
38. Have you felt downhearted and blue?	1	2	3	4	5	6
39. Did you feel worn out?	1	2	3	4	5	6
40. Have you been a happy person?	1	2	3	4	5	6
41. Did you feel tired?	1	2	3	4	5	6

42. During the **past four weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How **TRUE** or **FALSE** is each of the following statements for you?

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
43. I seem to get sick a little easier than other people.	1	2	3	4	5
44. I am as healthy as anybody I know.	1	2	3	4	5
45. I expect my health to get worse.	1	2	3	4	5
46. My health is excellent.	1	2	3	4	5

Personal Beliefs

The following items describe feelings that one may have about their appearance and attractiveness. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
47. I believe that physical attractiveness is important in day-to-day social interaction.	1	2	3	4	5
48. I believe that physical attractiveness is important in acquiring a mate (e.g., spouse, significant other).	1	2	3	4	5
49. I believe that physical attractiveness is important in attracting a sexual partner.	1	2	3	4	5
50. My breasts have always been an important part of my sexuality.	1	2	3	4	5
51. Physical and sexual attractiveness have always been very important to me.	1	2	3	4	5

The following items relate specifically to your feelings about the appearance of your breasts. Please circle the answer that best describes the way you now feel.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I feel whole.	1	2	3	4	5
2. I like the way my blouses/sweaters fit.	1	2	3	4	5
3. I like the way I look in a bathing suit.	1	2	3	4	5
4. My bra fits comfortably.	1	2	3	4	5
5. I feel attractive.	1	2	3	4	5
6. I think of my cancer when I look at my breasts.	1	2	3	4	5
7. I like the appearance of my breasts.	1	2	3	4	5
8. My significant other likes the appearance of my breasts.	1	2	3	4	5
9. I feel self-conscious during sexual activity because of the appearance of my breasts.	1	2	3	4	5

Health Complaints

1. The following items describe bodily symptoms that most of us have experienced at one time or another. Please circle the number that corresponds best with the way you have felt during the PAST WEEK. Please answer all questions. Do not think too long before answering.

	Not at all	A little/slightly	A great deal/quite a bit	Extremely could not have been worse
Heart rate increase	1	2	3	4
Feeling hot all over	1	2	3	4
Sweating all over	1	2	3	4
Sweating in a particular part of the body	1	2	3	4
Pulse in neck	1	2	3	4
Pounding in head	1	2	3	4
Dizziness	1	2	3	4
Blurring of vision	1	2	3	4
Feeling faint	1	2	3	4
Everything appearing unreal	1	2	3	4
Nausea	1	2	3	4
Butterflies in stomach	1	2	3	4
Pain or ache in stomach	1	2	3	4
Stomach churning	1	2	3	4
Desire to pass water	1	2	3	4
Mouth becoming dry	1	2	3	4
Difficulty swallowing	1	2	3	4
Muscles in neck aching	1	2	3	4
Legs feeling weak	1	2	3	4
Muscles twitching or jumping	1	2	3	4
Tense feeling across forehead	1	2	3	4
Tense feeling in jaw muscles	1	2	3	4

2. Here is a list of health problems that usually last for some time. Do you have any of the following problems? (Check all that apply)

Yes No

— — Asthma
 — — Chronic bronchitis or emphysema
 — — Arthritis or rheumatism
 — — High blood pressure
 — — Angina
 — — Congestive heart failure
 — — History of stroke
 — — Cancer (other than breast or skin cancer: specify type _____)
 — — Diabetes
 — — Chronic back trouble
 — — Lupus
 — — Scleroderma
 — — Other _____

3. Approximately how many times during the PAST SIX MONTHS have you had to visit a doctor because of physical symptoms or follow-up care **related** to your breast reconstruction? Please check one of the following.
 5 or less times
 6 to 10 times
 More than 10 times

4. Approximately how many times during the PAST SIX MONTHS have you had to visit a doctor because of physical symptoms related to treatment for medical problems **unrelated** to your breast cancer or to your reconstruction? Please check one of the following.
 5 or less times
 6 to 10 times
 More than 10 times

We would like to learn more about you and your background. Please answer the following questions so that we may better understand your responses.

1. Please check the best description of your current marital situation.
 Single
 Living with a significant other
 Married
 Widowed
 Divorced
 Separated

2. We are interested in knowing the degree to which you have participated in regular exercise habits DURING THE PAST SIX MONTHS. The following examples list various exercise activities in terms of their vigorousness and duration.

MILD EXERCISE: leisurely walking, gardening, leisurely biking.
MODERATE EXERCISE: 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming, etc.
VIGOROUS EXERCISE: 30 minutes or more of aerobics, running, basketball, stair-stepper, etc.

Please review the following statements and select the one answer which best describes your exercise habits over the past six months.

 I do not exercise
 I do mild exercise 1 to 2 times per week
 I do mild exercise 3 or more times per week
 I do moderate exercise 1 to 2 times per week
 I do moderate exercise 3 or more times per week
 I do vigorous exercise 1 to 2 times per week
 I do vigorous exercise 3 or more times per week

3. When you did take part in the physical activity or exercise which you checked in Questions 4, for how long did you usually maintain it?
 15 minutes or less
 Greater than 15 minutes, but less than 45 minutes
 45 minutes or more
 I do not exercise

4. Now we are interested in whether or not your exercise routine includes abdominal/stomach and back exercises, such as sit-ups or curl-ups. During the past six months, on average, how many times per week did you specifically exercise your back or stomach muscles?
 Not at all
 Once a week or less
 Two to three times per week
 More than three times per week

5. Do you currently smoke cigarettes? Yes ____ No ____

6. If you smoke cigarettes, how many packages of cigarettes do you smoke in an average day?
____ less than 1/2 pack per day
____ 1/2 to 1 pack per day
____ more than 1 pack per day

7. Do you currently drink any alcoholic beverages (beer, wine, liquor)? Yes ____ No ____

8. If you currently do drink alcoholic beverages, how many drinks do you consume
in an average week (including the weekend)? _____

9. Please check the statement that best describes your current employment situation:
Read all options carefully before checking just one.

____ I am currently employed outside of the home,
or am seeking employment outside of the home
____ I am currently employed outside of the home, on paid or unpaid leave
____ I am a homemaker, student, or retired person
____ I am disabled due to my breast cancer
____ I am disabled but not due to my breast cancer
____ Other (please specify): _____

10. If you are currently working outside of the home, how many hours per week do you spend on that work?

____ Not currently working outside of the home
____ Less than 15 hours per week
____ 15 to 40 hours per week
____ More than 40 hours per week

11. Which of the following best describes your work history?

____ I have not worked in the past three years
____ I have worked intermittently for the past three years
____ I have been continuously employed for the past three years

12. If you were employed prior to breast reconstruction, what impact has the reconstruction had on your employment?

____ It has not been affected
____ I had to reduce my hours or type of work
____ I have left my job.

13. About what was your total family income from all sources last year before taxes? (Count all income for all household members who live with you. Circle one number for the category that includes your approximate family income last year.)

(Circle one number)

less than \$15,000	1
\$15,000 to \$24,999	2
\$25,000 to \$49,999	3
\$50,000 to \$75,000	4
more than \$75,000	5

14. How many persons other than yourself are dependent on your family's income? _____

Fact-B (Version 3)

Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past seven days.

During the past seven days:

Physical Well-Being

	not at all	a little bit	some what	quite a bit	very much
1. I have a lack of energy.	0	1	2	3	4
2. I have nausea.	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
4. I have pain.	0	1	2	3	4
5. I am bothered by side effects of treatment.	0	1	2	3	4
6. I feel sick.	0	1	2	3	4
7. I am forced to spend time in bed.	0	1	2	3	4
8. Looking at the above seven questions, how much would you say your Physical Well-Being affects your quality of life?	0	1	2	3	4

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:

Social/Family Well-Being

	not at all	a little bit	some what	quite a bit	very much
9. I feel distant from my friends.	0	1	2	3	4
10. I get emotional support from my family.	0	1	2	3	4
11. I get support from my friends and neighbors.	0	1	2	3	4
12. My family has accepted my illness.	0	1	2	3	4
13. Family communication about my illness is poor.	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support).	0	1	2	3	4

15. Have you been sexually active during the past year?

No

Yes If yes: I am satisfied with my sex life.

0 1 2 3 4

16. Looking at the above seven questions, how much would you say your **Social/Family Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days: **Additional Concerns**

During the past seven days: Additional Concerns	not at all	a little bit	some what	quite a bit	very much
35. I have been short of breath.	0	1	2	3	4
36. I am self-conscious about the way I dress.	0	1	2	3	4
37. My arms are swollen or tender.	0	1	2	3	4
38. I feel sexually attractive.	0	1	2	3	4
39. I have been bothered by hair loss.	0	1	2	3	4
40. I worry about the risk of cancer in other family members.	0	1	2	3	4
41. I worry about the effect of stress on my illness.	0	1	2	3	4
42. I am bothered by a change in weight.	0	1	2	3	4
43. I am able to feel like a woman.	0	1	2	3	4

44. Looking at the above nine questions, how much would you say these **Additional Concerns** affect your quality of life?

(circle one number)

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST SEVEN DAYS, INCLUDING TODAY. Circle only one number for each problem, and do not skip any items. If you change your mind, erase your first mark carefully.

HOW MUCH WERE YOU DISTRESSED BY:		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
1. Nervousness or shakiness inside		1	0	1	2	3
2. Faintness or dizziness		2	0	1	2	3
3. The idea that someone else can control your thoughts		3	0	1	2	3
4. Feeling others are to blame for most of your troubles		4	0	1	2	3
5. Trouble remembering things		5	0	1	2	3
6. Feeling easily annoyed or irritated		6	0	1	2	3
7. Pains in heart or chest		7	0	1	2	3
8. Feeling afraid in open spaces		8	0	1	2	3
9. Thoughts of ending your life		9	0	1	2	3
10. Feeling that most people cannot be trusted		10	0	1	2	3
11. Poor appetite		11	0	1	2	3
12. Suddenly scared for no reason		12	0	1	2	3
13. Temper outbursts that you could not control		13	0	1	2	3
14. Feeling lonely even when you are with people		14	0	1	2	3
15. Feeling blocked in getting things done		15	0	1	2	3
16. Feeling lonely		16	0	1	2	3
17. Feeling blue		17	0	1	2	3
18. Feeling no interest in things		18	0	1	2	3
19. Feeling fearful		19	0	1	2	3
20. Your feelings being easily hurt		20	0	1	2	3
21. Feeling that people are unfriendly or dislike you		21	0	1	2	3
22. Feeling inferior to others		22	0	1	2	3
23. Nausea or upset stomach		23	0	1	2	3
24. Feeling that you are watched or talked about by others		24	0	1	2	3
25. Trouble falling asleep		25	0	1	2	3
26. Having to check and double check what you do		26	0	1	2	3
27. Difficulty making decisions		27	0	1	2	3
28. Feeling afraid to travel on buses, subways or trains		28	0	1	2	3
29. Trouble catching your breath		29	0	1	2	3
30. Hot or cold spells		30	0	1	2	3
31. Having to avoid certain things, places or activities because they frighten you		31	0	1	2	3
32. Your mind going blank		32	0	1	2	3
33. Numbness or tingling in parts of your body		33	0	1	2	3
34. The idea that you should be punished for your sins		34	0	1	2	3
35. Feeling hopeless about the future		35	0	1	2	3

HOW MUCH WERE YOU DISTRESSED BY:

		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4

Pre-Surgery Evaluation
Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor

(For office use only)
REGISTRATION # _____

I. Personal Information

Today's Date: _____

Your Name: _____

Date of Birth: _____ SS#: _____

Address: _____

City, State, Zip: _____

Telephone: (home) _____ - _____ - _____ (work) _____ - _____ - _____

Contact person or relative who does not live with you:

Name _____

Telephone: (home) _____ - _____ - _____

With regards to your mastectomy:

Date of Mastectomy _____ General Surgeon's name _____

Hospital Name _____ City, State _____

Decision to Seek Surgery

We are interested in why you have chosen to seek breast reconstruction. The following statements reflect some of the reasons why women seek breast reconstruction following a mastectomy. For each statement, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I want to feel whole again.	1	2	3	4	5
2. I want to feel the way I did before my cancer.	1	2	3	4	5
3. I want to wear the same type of clothing I was able to before my breast cancer.	1	2	3	4	5
4. I want to feel attractive.	1	2	3	4	5
5. I want to avoid the need to wear a prosthesis.	1	2	3	4	5
6. I want to have breast reconstruction so that I am not constantly reminded that I had cancer.	1	2	3	4	5
7. I am having surgery mainly because my significant other wants me to.	1	2	3	4	5
8. I want to be more attractive to my significant other.	1	2	3	4	5
9. I want to feel less self-conscious during sexual activity.	1	2	3	4	5
10. I want to improve my relationship with my significant other.	1	2	3	4	5
11. I think that breast reconstruction will enhance my emotional health and self-worth.	1	2	3	4	5

General Health Survey

1. In general, would you say your health is: (Circle One Number)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now? (Circle One Number)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

In one year from now, how do you think your health will be?

(Circle One Number)

Much better than today	1
Somewhat better than today	2
About the same as today	3
Somewhat worse than today	4
Much worse than today	5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes Limited a Lot	Yes Limited a Little	Not Limited at All
--	-------------------------	----------------------------	--------------------------

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

1	2	3
---	---	---

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf

1	2	3
---	---	---

5. Lifting or carrying groceries

1	2	3
---	---	---

6. Climbing several flights of stairs

1	2	3
---	---	---

7. Climbing one flight of stairs

1	2	3
---	---	---

8. Bending, kneeling or stooping

1	2	3
---	---	---

9. Walking more than one mile

1	2	3
---	---	---

10. Walking several blocks

1	2	3
---	---	---

11. Walking one block

1	2	3
---	---	---

12. Bathing or dressing yourself

1	2	3
---	---	---

13. Bending over to brush your teeth

1	2	3
---	---	---

14. Sitting up in bed when you awake in the morning

1	2	3
---	---	---

15. Doing the dishes

1	2	3
---	---	---

16. Arising from a chair

1	2	3
---	---	---

17. Grasping for something, like reaching for a glass from the cupboard

1	2	3
---	---	---

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)	Yes	No
18. Cut down the amount of time you spent on work or other activities	1	2
19. Accomplished less than you would like	1	2
20. Were limited in the kind of work or other activities	1	2
21. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)	Yes	No
22. Cut down the amount of time you spent on work or other activities	1	2
23. Accomplished less than you would like	1	2
24. Didn't do work or other activities as carefully as usual	1	2

25. During the **past four weeks**, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

(Circle One Number)	
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

26. How much **bodily** pain have you had during the **past four weeks**?

(Circle One Number)	
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

27. During the **past four weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)	
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

For each of the following statements, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True 1	Mostly True 2	Not Sure 3	Mostly False 4	Definitely False 5
28. My breasts are without pain.					
29. My abdomen is sore and painful.	1	2	3	4	5
30. I am frequently troubled by headaches.	1	2	3	4	5
31. My abdomen feels tight.	1	2	3	4	5
32. I have back pain.	1	2	3	4	5

These questions are about how you feel and how things have been with you **during the past four weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past four weeks** . . .

(Circle One Number on Each Line)	All of the Time 1	Most of the Time 2	A Good Bit of the Time 3	Some of the Time 4	A Little of the Time 5	None of the Time 6
33. Did you feel full of pep?	1	2	3	4	5	6
34. Have you been a very nervous person?	1	2	3	4	5	6
35. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Did you have a lot of energy?	1	2	3	4	5	6
38. Have you felt downhearted and blue?	1	2	3	4	5	6
39. Did you feel worn out?	1	2	3	4	5	6
40. Have you been a happy person?	1	2	3	4	5	6
41. Did you feel tired?	1	2	3	4	5	6

42. During the **past four weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
43. I seem to get sick a little easier than other people.	1	2	3	4	5
44. I am as healthy as anybody I know.	1	2	3	4	5
45. I expect my health to get worse.	1	2	3	4	5
46. My health is excellent.	1	2	3	4	5

Personal Beliefs

The following items describe feelings that one may have about their appearance and attractiveness. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
47. I believe that physical attractiveness is important in day-to-day social interaction.	1	2	3	4	5
48. I believe that physical attractiveness is important in acquiring a mate (e.g., spouse, significant other).	1	2	3	4	5
49. I believe that physical attractiveness is important in attracting a sexual partner.	1	2	3	4	5
50. My breasts have always been an important part of my sexuality.	1	2	3	4	5
51. Physical and sexual attractiveness have always been very important to me.	1	2	3	4	5

The following items relate specifically to your feelings about the appearance of your breasts. Please circle the answer that best describes the way you now feel.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I feel whole.	1	2	3	4	5
2. I like the way my blouses/sweaters fit.	1	2	3	4	5
3. I like the way I look in a bathing suit.	1	2	3	4	5
4. My bra fits comfortably.	1	2	3	4	5
5. I feel attractive.	1	2	3	4	5
6. I think of my cancer when I look at my breasts.	1	2	3	4	5
7. I like the appearance of my breasts.	1	2	3	4	5
8. My significant other likes the appearance of my breasts.	1	2	3	4	5
9. I feel self-conscious during sexual activity because of the appearance of my breasts.	1	2	3	4	5

Health Complaints

1. The following items describe bodily symptoms that most of us have experienced at one time or another. Please circle the number that corresponds best with the way you have felt during the PAST WEEK. Please answer all questions. Do not think too long before answering.

	Not at all	A little/ slightly	A great deal/ quite a bit	Extremely could not have been worse
Heart rate increase	1	2	3	4
Feeling hot all over	1	2	3	4
Sweating all over	1	2	3	4
Sweating in a particular part of the body	1	2	3	4
Pulse in neck	1	2	3	4
Pounding in head	1	2	3	4
Dizziness	1	2	3	4
Blurring of vision	1	2	3	4
Feeling faint	1	2	3	4
Everything appearing unreal	1	2	3	4
Nausea	1	2	3	4
Butterflies in stomach	1	2	3	4
Pain or ache in stomach	1	2	3	4
Stomach churning	1	2	3	4
Desire to pass water	1	2	3	4
Mouth becoming dry	1	2	3	4
Difficulty swallowing	1	2	3	4
Muscles in neck aching	1	2	3	4
Legs feeling weak	1	2	3	4
Muscles twitching or jumping	1	2	3	4
Tense feeling across forehead	1	2	3	4
Tense feeling in jaw muscles	1	2	3	4

2. Here is a list of health problems that usually last for some time. Do you have any of the following problems? (Check all that apply)

Yes No

- Asthma
- Chronic bronchitis or emphysema
- Arthritis or rheumatism
- High blood pressure
- Angina
- Congestive heart failure
- History of stroke
- Cancer (other than breast or skin cancer: specify type _____)
- Diabetes
- Chronic back trouble
- Lupus
- Scleroderma
- Other _____

We would like to learn more about you and your background. Please answer the following questions so that we may better understand your responses.

1. Do you consider yourself primarily:

- African-American
- Asian or Pacific Islander
- Hispanic
- Native American
- White
- Other (please specify): _____

2. Highest level of education completed?

- Less than high school
- Completed high school
- Some college
- Completed college
- Some graduate work
- Graduate degree

3. Please check the best description of your current marital situation.

- Single
- Living with a significant other
- Married
- Widowed
- Divorced
- Separated

4. We are interested in knowing the degree to which you have participated in regular exercise habits DURING THE PAST SIX MONTHS. The following examples list various exercise activities in terms of their vigorousness and duration.

MILD EXERCISE: leisurely walking, gardening, leisurely biking.

MODERATE EXERCISE: 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming, etc.

VIGOROUS EXERCISE: 30 minutes or more of aerobics, running, basketball, stair-stepper, etc.

Please review the following statements and select the one answer which best describes your exercise habits over the past six months.

- I do not exercise
- I do mild exercise 1 to 2 times per week
- I do mild exercise 3 or more times per week
- I do moderate exercise 1 to 2 times per week
- I do moderate exercise 3 or more times per week
- I do vigorous exercise 1 to 2 times per week
- I do vigorous exercise 3 or more times per week

4a. When you did take part in the physical activity or exercise which you checked in Question 4, for how long did you usually maintain it?

- 15 minutes or less
- Greater than 15 minutes, but less than 45 minutes
- 45 minutes or more
- I do not exercise

5. Now we are interested in whether or not your exercise routine includes abdominal/stomach and back exercises, such as sit-ups or curl-ups. During the past six months, on average, how many times per week did you specifically exercise your back or stomach muscles?

- Not at all
- Once a week or less
- Two to three times per week
- More than three times per week

6. Do you currently smoke cigarettes? Yes ____ No ____

7. If you smoke cigarettes, how many packages of cigarettes do you smoke in an average day?

- less than 1/2 pack per day
- 1/2 to 1 pack per day
- more than 1 pack per day

8. Do you currently drink any alcoholic beverages (beer, wine, liquor)? Yes ____ No ____

9. If you currently do drink alcoholic beverages, how many drinks do you consume in an average week (including the weekend)? _____

10. Please check the statement that best describes your current employment situation:
Read all options carefully before checking just one.

- I am currently employed outside of the home, or am seeking employment outside of the home
- I am currently employed outside of the home, on paid or unpaid leave
- I am a homemaker, student, or retired person
- I am disabled due to my breast cancer
- I am disabled but not due to my breast cancer
- Other (please specify): _____

11. If you are currently working outside of the home, how many hours per week do you spend on that work?

- Not currently working outside of the home
- Less than 15 hours per week
- 15 to 40 hours per week
- More than 40 hours per week

12. Which of the following best describes your work history?

I have not worked in the past three years
 I have worked intermittently for the past three years
 I have been continuously employed for the past three years

13. What type(s) of medical insurance coverage do you carry?
(Check yes or no for each one.)

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Blue Cross/Blue Shield
<input type="checkbox"/>	<input type="checkbox"/>	Other Private Insurance (e.g. Aetna, Travelers, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	HMO or Managed Care program (which? _____)
<input type="checkbox"/>	<input type="checkbox"/>	Medicare
<input type="checkbox"/>	<input type="checkbox"/>	Medicaid
<input type="checkbox"/>	<input type="checkbox"/>	None
<input type="checkbox"/>	<input type="checkbox"/>	Other (Which? _____)

14. Does the medical insurance which you carry cover breast reconstruction surgery?

Yes _____ No _____ Don't Know _____

15. About what was your total family income from all sources last year before taxes? (Count all income for all household members who live with you. Circle one number for the category that includes your approximate family income last year.)

(Circle one number)

less than \$15,000	1
\$15,000 to \$24,999	2
\$25,000 to \$49,999	3
\$50,000 to \$75,000	4
more than \$75,000	5

16. How many persons other than yourself are dependent on your family's income? _____

Fact-B (Version 3)

Michigan Breast Reconstruction Outcome Study

University of Michigan, Ann Arbor

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past seven days.

During the past seven days:

Physical Well-Being

	not at all	a little bit	some what	quite a bit	very much
1. I have a lack of energy.	0	1	2	3	4
2. I have nausea.	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
4. I have pain.	0	1	2	3	4
5. I am bothered by side effects of treatment.	0	1	2	3	4
6. I feel sick.	0	1	2	3	4
7. I am forced to spend time in bed.	0	1	2	3	4

8. Looking at the above seven questions, how much would you say your **Physical Well-Being** affects your quality of life?

(circle one number)

0	1	2	3	4	5	6	7	8	9	10
not at all										very much

During the past seven days:

Social/Family Well-Being

	not at all	a little bit	some what	quite a bit	very much
9. I feel distant from my friends.	0	1	2	3	4
10. I get emotional support from my family.	0	1	2	3	4
11. I get support from my friends and neighbors.	0	1	2	3	4
12. My family has accepted my illness.	0	1	2	3	4
13. Family communication about my illness is poor.	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support).	0	1	2	3	4

15. Have you been sexually active during the past year?

No

Yes If yes: I am satisfied with my sex life.

0	1	2	3	4
---	---	---	---	---

16. Looking at the above seven questions, how much would you say your **Social/Family Well-Being** affects your quality of life?

(circle one number)

0	1	2	3	4	5	6	7	8	9	10
not at all										very much

During the past seven days:
Relationship With The Doctor

	not at all	a little bit	some what	quite a bit	very much
17. I have confidence in my doctor(s).	0	1	2	3	4
18. My doctor is available to answer my questions.	0	1	2	3	4

19. Looking at the above two questions, how much would you say your **Relationship With The Doctor** affects your quality of life?

(circle one number)

0	1	2	3	4	5	6	7	8	9	10
not at all										very much

During the past seven days:
Emotional Well-Being

20. I feel sad.	0	1	2	3	4
21. I am proud of how I'm coping with my illness.	0	1	2	3	4
22. I am losing hope in the fight against my illness.	0	1	2	3	4
23. I feel nervous.	0	1	2	3	4
24. I worry about dying.	0	1	2	3	4
25. I worry that my condition will get worse.	0	1	2	3	4

26. Looking at the above six questions, how much would you say your **Emotional Well-Being** affects your quality of life?

(circle one number)

0	1	2	3	4	5	6	7	8	9	10
not at all										very much

During the past seven days:
Functional Well-Being

27. I am able to work (include the work in home).	0	1	2	3	4
28. My work (include work in home) is fulfilling.	0	1	2	3	4
29. I am able to enjoy life.	0	1	2	3	4
30. I have accepted my illness.	0	1	2	3	4
31. I am sleeping well.	0	1	2	3	4
32. I am enjoying the things I usually do for fun.	0	1	2	3	4
33. I am content with the quality of my life right now.	0	1	2	3	4

34. Looking at the above seven questions, how much would you say your **Functional Well-Being** affects your quality of life?

(circle one number)

0	1	2	3	4	5	6	7	8	9	10
not at all										very much

During the past seven days:

Additional Concerns

35. I have been short of breath.	0	1	2	3	4
36. I am self-conscious about the way I dress.	0	1	2	3	4
37. My arms are swollen or tender.	0	1	2	3	4
38. I feel sexually attractive.	0	1	2	3	4
39. I have been bothered by hair loss.	0	1	2	3	4
40. I worry about the risk of cancer in other family members.	0	1	2	3	4
41. I worry about the effect of stress on my illness.	0	1	2	3	4
42. I am bothered by a change in weight.	0	1	2	3	4
43. I am able to feel like a woman.	0	1	2	3	4

44. Looking at the above nine questions, how much would you say these **Additional Concerns** affect your quality of life?

(circle one number)

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST SEVEN DAYS, INCLUDING TODAY. Circle only one number for each problem, and do not skip any items. If you change your mind, erase your first mark carefully.

HOW MUCH WERE YOU DISTRESSED BY:	Extremely					
	Not At All	A Little Bit	Moderately	Quite A Bit	Extremely	
1. Nervousness or shakiness inside	1	0	1	2	3	4
2. Faintness or dizziness	2	0	1	2	3	4
3. The idea that someone else can control your thoughts	3	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	4	0	1	2	3	4
5. Trouble remembering things	5	0	1	2	3	4
6. Feeling easily annoyed or irritated	6	0	1	2	3	4
7. Pains in heart or chest	7	0	1	2	3	4
8. Feeling afraid in open spaces	8	0	1	2	3	4
9. Thoughts of ending your life	9	0	1	2	3	4
10. Feeling that most people cannot be trusted	10	0	1	2	3	4
11. Poor appetite	11	0	1	2	3	4
12. Suddenly scared for no reason	12	0	1	2	3	4
13. Temper outbursts that you could not control	13	0	1	2	3	4
14. Feeling lonely even when you are with people	14	0	1	2	3	4
15. Feeling blocked in getting things done	15	0	1	2	3	4
16. Feeling lonely	16	0	1	2	3	4
17. Feeling blue	17	0	1	2	3	4
18. Feeling no interest in things	18	0	1	2	3	4
19. Feeling fearful	19	0	1	2	3	4
20. Your feelings being easily hurt	20	0	1	2	3	4
21. Feeling that people are unfriendly or dislike you	21	0	1	2	3	4
22. Feeling inferior to others	22	0	1	2	3	4
23. Nausea or upset stomach	23	0	1	2	3	4
24. Feeling that you are watched or talked about by others	24	0	1	2	3	4
25. Trouble falling asleep	25	0	1	2	3	4
26. Having to check and double check what you do	26	0	1	2	3	4
27. Difficulty making decisions	27	0	1	2	3	4
28. Feeling afraid to travel on buses, subways or trains	28	0	1	2	3	4
29. Trouble catching your breath	29	0	1	2	3	4
30. Hot or cold spells	30	0	1	2	3	4
31. Having to avoid certain things, places or activities because they frighten you	31	0	1	2	3	4
32. Your mind going blank	32	0	1	2	3	4
33. Numbness or tingling in parts of your body	33	0	1	2	3	4
34. The idea that you should be punished for your sins	34	0	1	2	3	4
35. Feeling hopeless about the future	35	0	1	2	3	4

HOW MUCH WERE YOU DISTRESSED BY:

		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4



MICHIGAN BREAST RECONSTRUCTION OUTCOME STUDY

POST-SURGERY PHYSICIAN VISIT LOG

This log should be used by all participants in the MBROS study to record their post-surgical outpatient visits to any physician's office. Every four months for two years, the old logs will be collected and new logs sent to each patient. Please try and record your visit immediately after seeing your physician so as to try and keep the best records possible of your post-surgical treatments. If you have any questions, please contact the project coordinator at (313) 936-7321.

Your Name _____

Your Social Security # _____

Your Telephone Number _____

Continue on Reverse

APPENDIX B
DATABASE ENTRY SCREENS

Demographic Information

Date Questionnaire	Complete	<input type="checkbox"/>	Study IC	<input type="checkbox"/>	
First name	██████████	Middle initial	████	Status	<input type="checkbox"/>
DOB	██████████	Ss number	██████████		
Address	██████████	City	██████████	Country	██████████
Address :	██████████	State	████		
Home phone	(████) █████	Zip	██████████		
Contact Person	██████████	Work phone	(████) █████		
Phone	(████) █████				
Date of mastectomy	██████████	To select a record, dial the studyid number Then select "Goto"			
General Surgeon	First	Last	██████████		
Hospital	██████████	Type of Reconstruction	██████████		
City	██████████	Left	<input type="checkbox"/>	Both	<input type="checkbox"/>
State	██████████	Immediate	<input type="checkbox"/>	Delayed	<input type="checkbox"/>
Date of Reconstruction	██████████	Delayed	<input type="checkbox"/>	Immediate	<input type="checkbox"/>
Plastic Surgeo	██████████	Date	██████████	Delayed	<input type="checkbox"/>
Hospital Name	██████████	Pedicle tran	<input type="checkbox"/>	Pedicle tran	<input type="checkbox"/>
Complication	██████████	Free Tram	<input type="checkbox"/>	Free Tram	<input type="checkbox"/>
	██████████	Implan	<input type="checkbox"/>	Implan	<input type="checkbox"/>
	██████████	Lat Dors	<input type="checkbox"/>	Lat Dors	<input type="checkbox"/>
	██████████	Reductio	<input type="checkbox"/>	Reductio	<input type="checkbox"/>



Go to Quest 1/

Fauent Data Sheet

Name	SS number	Study ID				
DOB	Work phone	Status				
Home phone		Hospital number				
Tissue	Diagnosis	Left Date of Dx	Right Date of Dx	Cancer Treatment	Operation -- Left	Operation -- Right
<input type="checkbox"/>	Infiltrating ductal carcinoma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Left Date <input type="text"/>	Right Date <input type="text"/>
<input type="checkbox"/>	Ductal carcinoma in situ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lumpectomy	Lumpectomy
<input type="checkbox"/>	Infiltrating lobular carcinoma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Subcutaneous mastectomy	Subcutaneous mastectomy
<input type="checkbox"/>	Lobular carcinoma in situ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Simple mastectomy	Simple mastectomy
<input type="checkbox"/>	Inflammatory carcinoma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Modified radical mastectomy	Modified radical mastectomy
<input type="checkbox"/>	Cystosarcoma phyllodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radical mastectomy	Radical mastectomy
<input type="checkbox"/>	Family history of breast cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Radiation Therapy	Left Date: <input type="text"/> to <input type="text"/>
<input type="checkbox"/>	Other (Specify) <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Right Date: <input type="text"/> to <input type="text"/>	Right Date: <input type="text"/> to <input type="text"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adjuvant Chemotherapy Dates: From <input type="text"/> to <input type="text"/>	

Reconstruction		Additional		Reconstructive procedures and Date	
Surgeon	Hospital	L	R	Implant Exchange	
Left Date: <input type="text"/>	Immediate <input type="checkbox"/>	Delayed <input type="checkbox"/>		Capsulectomy/Capsulotomy	
Right Date: <input type="text"/>	Immediate <input type="checkbox"/>	Delayed <input type="checkbox"/>		Nipple-Areolar Reconstruction	
				Revision/Debulking	TRAM Flap
				Scar Revision	
				Contralat Reduct Mammaplast	
				Contralateral Mastopex	
				Contralateral Augmentation	
				Other (Specify) <input type="text"/>	
Go to Complications Sheet					

To select a record, dial the study id number. Then select "Goto".

1

Type of Reconstruction

L R

Implant

Expander/Implant

Pedicle TRAM Flap

Free TRAM Flap

Lat Dors

Reduction

Other (Specify)

"Firsthalf" databases
Study 1C
Status
Date complete
Decision to Seek Sb

<u>Physical</u> health	18. amount of time	19. accomplished less
	20. kind or worse	21. difficult

Questionnaire 1-1

Questionnaire 1-1

	<u>Emotional Problem</u>
1.	feel whole
2.	pre cance
3.	clothin!
4.	attractiv
22.	amount of tim
23.	accomplished les
24.	carefull

6. reminder	7. s.o. want:	8. attractive to s.c	9. sex	0. relationship	1. emotional healt	2. During the past 4 weeks,	25. social activitie	26. bodily pain	27. pain interfer-	How true for you.	28. breast pain
-------------	---------------	----------------------	--------	-----------------	--------------------	-----------------------------	----------------------	-----------------	--------------------	-------------------	-----------------

General Health Survey

Activités

ACTIVITE	DURANT une <u>periode</u> de 4 semaines.
3. vigorou:	33. full of pei
4. moderate	34. nervou:
5. liftin!	35. dump:
6. climb severa	36. calm
7. climb on!	37. energi
8. bend	38. blue
9. mile	39. worn ou
0. several block	40. happy
1. one bloc	41. tirec
2. bathin!	42. social activitie
3. brush teetl	How <u>true</u> or <u>false</u> .
4. sit up in be:	43. sick easie
dishes:	44. as health
6. arise fron	45. worse
7. start	46. excellen

<u>During the past 4 weeks,</u>			
25. social activitie			
26. bodily pain			
27. pain interter			
<u>How true for you.</u>			
28. breast pain			
29. abdomen sor			
30. headache			
31. abdomen tigh			
32. back pain			

During the past 4 weeks:	
33.	full of <u>pep</u>
34.	nervous
35.	dumped
36.	calm
37.	energy
38.	blue
39.	worn out
40.	happy
41.	tired
42.	social activities
How true or false.	
43.	sick easier
44.	as healthy
45.	worse
46.	excellent

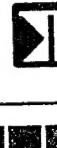
To select a record, dial the studyid numb
Then select "Goto"

Go to Quest 1E

BSI 1

Study IC
Status

How much were you distressed by

1. nervousness	21. people dislike yo	41. urges to brea	51. people take advantag
2. faintness:	22. interio	42. self-consciou	52. guilt.
3. someone else contri	23. nausea	43. uneasy in crowd	53. wrong with min
4. others to blam	24. watchet	44. never closi	
5. trouble rememberin	25. trouble falling aslee	45. terror	
6. easily annoyed	26. double chec	46. frequent argument	
7. pains	27. difficulty making decisio	47. nervous alon	
8. afraid in open	28. afraid to trav	48. no credi	
9. ending lif	29. trouble catching brea	49. restles	
10. not trus	30. hot spell:	50. worthlessness	
11. poor appetiti	31. avoid thing	51. people take advantag	
12. suddenly scare	32. mind going blan	52. guilt.	
13. temper outburst	33. numbnes:	53. wrong with min	
14. lonely with peopl	34. punishei		
15. blocker	35. hopeles:		
16. lonely	36. trouble concentratir	To select a record, dial the study id numb	
17. blue	37. weak	Then select "Goto"	
18. no interes	38. tense		
19. fearfu	39. death		
20. feelings easily hu	40. urges to bea		

FACT B3-1

Study IC

During the past seven day
Physical Well-Being

During the past seven day
Emotional Well-Being

During the past seven day
Additional Concerns

1. lack of energy
2. nausea
3. trouble meeting needs
4. pain
5. side effect:
6. sick
7. time in bed
8. physical well-being

During the past seven days, how well did you feel in these areas of social/family well-being?

9. distant from friends
10. family support
11. friend support
12. family acceptance
13. family communication
14. close to partner
15. sexually active
16. satisfied with self
17. social well-being

During the past seven days, how well did you feel in these areas of doctor relationship with the doctor?

18. doctor is available
19. relationship with the doctor

During the past seven days, how often have you felt well-being or social/family support?

During the past seven day
Functional Well-Being

27.	able to work	
28.	work is fulfilling	
29.	enjoy life	
30.	accepted illness	
31.	sleeping well	
32.	fun	
33.	content with QO	
34.	functional well-being	

35. short of breath
36. self-conscious dress
37. arms swollen
38. feel sexually attractive
39. hair loss
40. cancer in family
41. stress
42. change in weight
43. feel like a woman
44. additional concern

During the past seven day
Additional Concerns

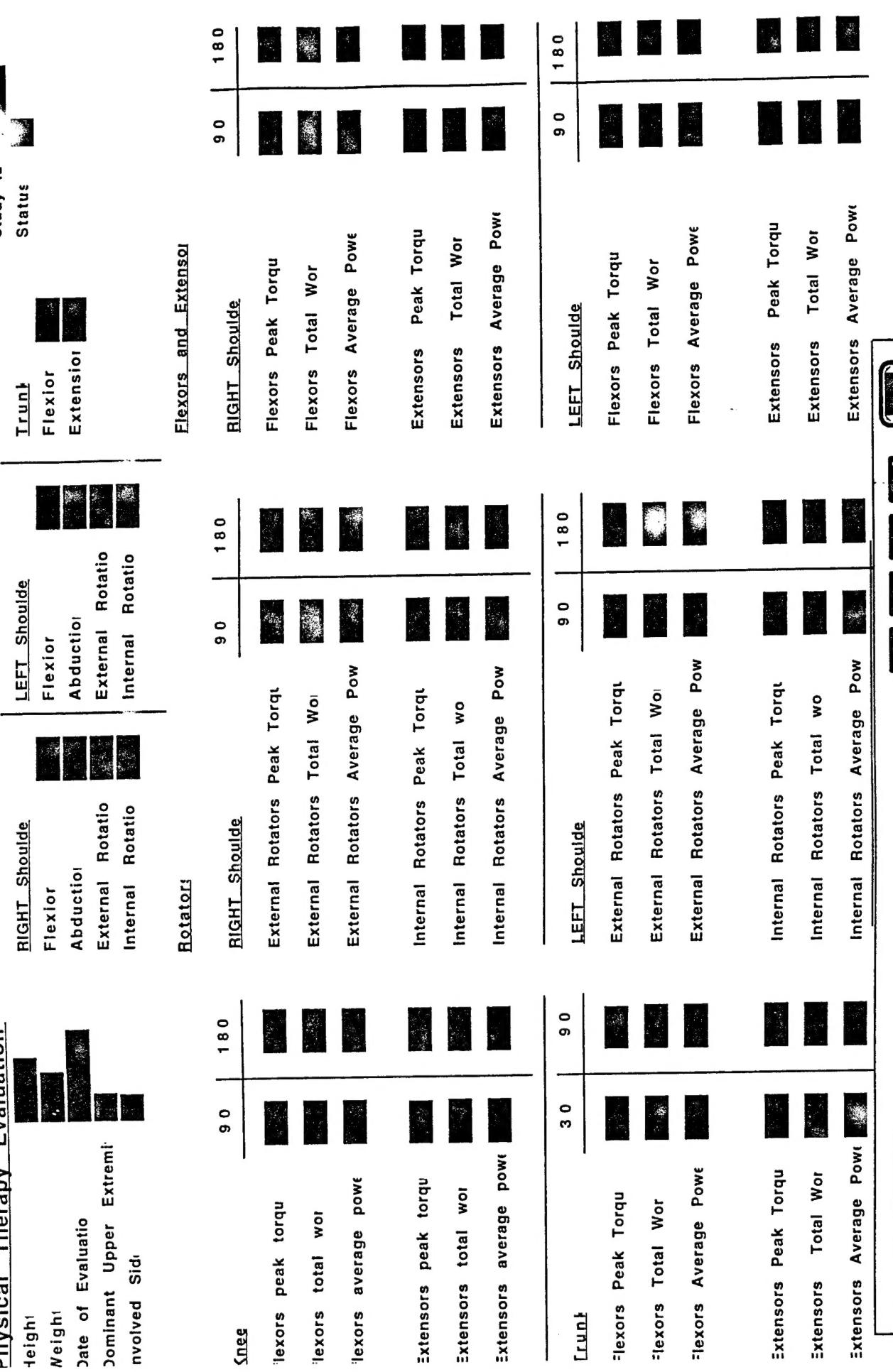
35. short of breath
36. self-conscious dress
37. arms swollen
38. feel sexually attracted
39. hair loss
40. cancer in family
41. stress
42. change in weight
43. feel like a woman
44. additional concern

To select a record, dial the studyid number
Then select "Goto"



Physical Therapy Evaluation

Height
Weight
Date of Evaluation
Dominant Upper Extremity
Involved Side



To select a record, dial the studyid numb
Then select "Goto"



FINANCIAL INFORMATION

Study
Status:

REGISTRATION NUMBER <input type="text"/>	Hospital <input type="text"/>	RECONSTRUCTIVE SURGEON: <input type="text"/>
RECONSTRUCTION <input type="text"/>	DATE OF SURGERY <input type="text"/>	
CATEGORY	1. IMMEDIATE IMPLANT, BILATERAL 2. IMMEDIATE IMPLANT, UNILATERAL 3. DELAYED IMPLANT, BILATERAL 4. DELAYED IMPLANT, UNILATERAL 5. IMMEDIATE PEDICLE TRAM, BILATERAL 6. IMMEDIATE PEDICLE TRAM, UNILATERAL 7. DELAYED PEDICLE TRAM, BILATERAL 8. DELAYED PEDICLE TRAM, UNILATERAL 9. IMMEDIATE FREE TRAM, BILATERAL 10. IMMEDIATE FREE TRAM, UNILATERAL 11. DELAYED FREE TRAM, BILATERAL 12. DELAYED FREE TRAM, UNILATERAL	
DATE OF ADMISSION <input type="text"/>	ICU DAYS <input type="text"/>	Insurance <input type="text"/>
DATE OF DISCHARGE <input type="text"/>		
LENGTH OF STAY <input type="text"/>		

CATEGORY "A" HOSPITAL COSTS RVU'S	
Orcost: <input type="text"/>	\$ <input type="text"/>
Othercost: <input type="text"/>	\$ <input type="text"/>
Room charge: <input type="text"/>	\$ <input type="text"/>
TOTAL = <input type="text"/>	

CODES	
MDISPRIM <input type="text"/>	
DRG01 <input type="text"/>	
Dop11 <input type="text"/>	
Dop12 <input type="text"/>	
Dop13 <input type="text"/>	

CATEGORY "B"	
RECONSTRUCTIVE SURGEON RVU COST <input type="text"/>	\$ <input type="text"/>
ANESTHESIOLOGY RVU COST <input type="text"/>	\$ <input type="text"/>
TOTAL RECONSTRUCTION PROFESSIONAL RVU = <input type="text"/>	
MEMO FIELDS:	
notes:psr <input type="text"/>	
notes:anes <input type="text"/>	

To select a record, dial the studyid numb
Then select "Goto"

CATEGORY "E"	
COMPLICATIONS: <input type="text"/>	
Notes: <input type="text"/>	
FACILITY RVU <input type="text"/>	
PROFESSIONAL RVU <input type="text"/>	
TOTAL COMPLICATION RVU = \$ <input type="text"/>	

CATEGORY "C"	
MASTECTOMY ALONE: <input type="text"/>	
GENERAL SURGEON <input type="text"/>	
HOSPITAL: <input type="text"/>	
ANESTHESIOLOGY RVU COST = \$ <input type="text"/>	

CATEGORY "D"	
EXPLANT TISSUE EXPANDER <input type="text"/>	
Bilateral or Unilateral? <input type="text"/>	
Inpatient or Outpatient? <input type="text"/>	
FACILITY RVU <input type="text"/>	
ANESTHESIOLOGY RVU <input type="text"/>	
TOTAL EXPLANT RVU = \$ <input type="text"/>	

TOTAL FINANCIAL IMPACT: ALL CATEGORIES A-E =

NOTES: \$